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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,032	12/07/2004	Sergio Capurro	BA-22902	2851
178	7590	08/28/2006	EXAMINER	
BUCKNAM AND ARCHER 1077 NORTHERN BOULEVARD ROSLYN, NY 11576			YABUT, DIANE D	
			ART UNIT	PAPER NUMBER
			3734	
DATE MAILED: 08/28/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/517,032	Applicant(s) CAPURRO, SERGIO	
	Examiner Diane Yabut	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/7/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Italy on 26 June 2002. It is noted, however, that applicant has not filed a certified copy of the GE02A000056 application as required by 35 U.S.C. 119(b).

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 7 December 2004 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

3. Claim 1 is objected to because of the following informalities: On lines 3-4 of Claim 1 it reads "a tubular metal shaft, the central portion of which is equipped" and should rather read --a tubular metal shaft with a central portion that is equipped--. Appropriate correction is required.

Note: On lines 3-4 of Claim 3 it reads "means of pinching" which does not invoke 35 U.S.C. 112, sixth paragraph.

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Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Scirica et al.** (U.S. Patent No. **5,908,428**) in view of **Munoz** (U.S. Patent No. **5,792,180**).

Claim 1: Scirica et al. discloses a surgical needle having two tips with a central portion equipped with a hole **212** through which emerges a surgical thread **34** that is anchored inside the needle (Figure 7 and col. 10, lines 21-26). Scirica et al. discloses the claimed device except for the needle being atraumatic and consisting of a tubular metal shaft.

Munoz teaches high strength atraumatic needles consisting of a tubular metal shaft (Figure 6, col. 5, lines 1-3). It would have been obvious to one of ordinary skill in the art at the time of invention to provide an atraumatic, tubular metal shaft, as taught by Munoz, to Scirica et al since it was known in the art that atraumatic, tubular metal shaft needles are commonly used in surgery to reduce the damage of punctured tissue of a patient.

Claim 2: Scirica et al. discloses a needle wherein its tips are beveled two oblique planes and the hole **212** through which the thread **34** passes involves only one wall of the hollow shaft (Figure 7).

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Claim 3: Scirica et al. discloses a needle wherein one end of the surgical thread **34** is inserted into the hole **212** of the needle and is anchored by means of pinching (Figure 7 and col. 10, lines 21-26).

6. Claims 4-6 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Scirica et al.** (U.S. Patent No. **5,908,428**) and **Munoz** (U.S. Patent No. **5,792,180**), as applied to Claim 1 above, and further in view of **Flagg et al.** (U.S. Patent No. **2,240,330**).

Claims 4-6: Scirica et al. discloses the claimed device, including a surgical thread being inserted into the hole of an atraumatic two-tipped needle, in combination with Munoz, except for being made to emerge from one end, the surgical thread being equipped with a knot and adapted to be drawn back inside the shaft towards the hole or be equipped with a knot in advance, being inserted into one end of the needle.

Flagg et al. teaches a surgical thread being equipped with a knot **13** emerging from one end and being adapted to be drawn back inside the shaft towards the hole or be equipped with a knot in advance or to be inserted into one end of the needle and emerged through the hole, in order to secure a suture to a needle hole (Figure 12, col. 2, lines 52-54). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a knot for anchoring the surgical thread, as taught by Flagg et al., to the combined device of Scirica et al. and Munoz, since it was known in the art that the use of knots to anchor threads to surgical needles and other fields of endeavor to limit the movement of a suture, thread, or cord through an opening using a knot is commonly used.

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Claim 13: Scirica et al. discloses the claimed device except for the surgical thread being fixed by means of two or more anchoring techniques

Flagg et al. teaches a surgical thread being fixed by means of two or more anchoring techniques to ensure a firm grip on the suture (col. 5, lines 3-8). It would have been obvious to one of ordinary skill in the art to provide a thread being fixed by means of two or more anchoring techniques, as taught by Flagg et al., to the combined device of Scirica et al. and Munoz, in order to ensure a firm anchoring grip on the suture.

7. Claims 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Scirica et al.** (U.S. Patent No. **5,908,428**) and **Munoz** (U.S. Patent No. **5,792,180**), as applied to Claim 1 above, and further in view of **Coplan** (U.S. Patent No. **3,918,455**).

Claims 7-11: Scirica et al. discloses the claimed device, including a needle with one end of the surgical thread being inserted into the hole and being anchored inside the atraumatic two-tipped needle by pinching, in combination with Munoz, except for being anchored by means of a scotch, a solid bar or a portion of tube, made of metal or plastic, the caliber of which is determined by the diameter of the needle, which is pushed down inside the needle from one of the two ends.

Coplan teaches a surgical thread, emerging from one end of the needle, being inserted and anchored, or fixed, in a hole in one end of a scotch **34**, a solid bar or a portion of tube, made of metal or plastic, the caliber of which is determined by the diameter of the needle, which is pushed down inside the

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needle from one of the two ends (Figure 4, col. 4, lines 55-63 and col. 6, lines 60-62). Coplan teaches that the use of the scotch **34** for a suture-needle combination reduces trauma at the site of tissue penetration and reduces hazard of suture tear-out (col. 1, lines 60-68). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a scotch, which is pushed down inside the needle from one of two ends, as taught by Coplan in order to reduce trauma at the site of tissue penetration and hazard of suture tear-out.

8. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Scirica et al.** (U.S. Patent No. **5,908,428**) and **Munoz** (U.S. Patent No. **5,792,180**), as applied to Claim 1 above, and further in view of **Borst et al.** (U.S. Pub. No. **20040260145**).

Claim 12: Scirica et al. and Munoz disclose the claimed device, including a surgical thread being inserted into an atraumatic two-tipped needle, except the thread being fixed between the coils of a tiny spring.

Borst et al. teaches a suture being fixed between the coils of a tiny spring (page 11, paragraph 132). It would have been obvious to one of ordinary skill in the art to fix a suture between the coils of a tiny spring, as taught by Borst et al., to the combined device of Scirica et al. and Munoz since it was known in the art that springs are used as flexible retaining means for sutures, threads, and cords.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. **Granger et al.** (U.S. Patent No. **5,569,301**) discloses the use of adhesive for anchoring a suture to a double-tipped needle; **Miller** (U.S. Patent No. **5,865,836**) discloses the use of shrink wrap type tubing for anchoring a suture to a double-tipped needle.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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A handwritten signature in black ink, appearing to read "MJ Hayes", written in a cursive style.

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER